

INTERLEUKIN GENETICS INC  
Form 10-Q  
November 04, 2005

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 10-Q

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934

For the Quarterly Period Ended September 30, 2005

Commission File Number: 0-23413

## INTERLEUKIN GENETICS, INC.

(Name of Registrant in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**135 Beaver Street, Waltham, MA**  
(Address of principal executive offices)

**94-3123681**  
(I.R.S. Employer  
Identification No.)  
**02452**  
(Zip Code)

Registrant's Telephone Number: (781) 398-0700

Securities registered pursuant to Section 12(b) of the Exchange Act:

**Common Stock, \$0.001 par value per  
share**

**Boston Stock Exchange**

Securities registered pursuant to Section 12(g) of the Exchange Act:

**Common Stock, \$0.001 par value per share**

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of October 31, 2005, there were 23,833,399 shares of the Registrant's Common Stock and 5,000,000 shares of the Registrant's Series A Preferred Stock, issued and outstanding.



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## PART I FINANCIAL INFORMATION

## Item 1. Financial Statements.

## INTERLEUKIN GENETICS, INC. AND SUBSIDIARY

## CONSOLIDATED BALANCE SHEETS

	September 30, 2005 (Unaudited)	December 31, 2004 (Audited)
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 4,293,260	\$ 4,528,425
Accounts receivable, net of allowance for doubtful accounts of \$0 in 2005 and 2004	365	10,131
Prepaid expenses and other current assets	185,055	182,819
Total current assets	4,478,680	4,721,375
<b>Fixed assets, net</b>	<b>965,150</b>	<b>1,142,087</b>
<b>Other assets</b>	<b>405,324</b>	<b>322,039</b>
<b>Total Assets</b>	<b>\$ 5,849,154</b>	<b>\$ 6,185,501</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 92,889	\$ 94,780
Accrued expenses	687,508	914,907
Deferred revenue	2,002,760	12,760
Commitments for funded research and development projects	334,966	408,544
Current portion of capital lease obligations	5,903	14,312
Total current liabilities	3,124,026	1,445,303
<b>Long-term notes payable (Face value: \$2,595,336)</b>	<b>1,556,119</b>	<b>1,209,713</b>
<b>Capital lease obligations, less current portion</b>		<b>2,978</b>
Total liabilities	4,680,145	2,657,994
<b>Stockholders equity:</b>		
Convertible preferred stock, Series A \$0.001 par value 6,000,000 shares authorized; 5,000,000 issued and outstanding at September 30, 2005 and December 31, 2004; aggregate liquidation preference of \$18,000,000 at September 30, 2005	5,000	5,000
Common stock, \$0.001 par value 75,000,000 shares authorized; 23,763,399 and 23,594,337 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	23,763	23,595
Additional paid-in capital	60,581,478	58,123,868
Accumulated deficit	(59,441,232)	(54,624,956)
Total stockholders equity	1,169,009	3,527,507
<b>Total liabilities and stockholders equity</b>	<b>\$ 5,849,154</b>	<b>\$ 6,185,501</b>

The accompanying notes are an integral part of these consolidated financial statements.

**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Unaudited)

	Three Months Ended September 30, 2005		Nine Months Ended September 30, 2005	
		2004 (As Restated)		2004 (As Restated)
<b>Revenue</b>	\$ 5,690	\$ 8,216	\$ 20,743	\$ 26,536
<b>Cost of revenue</b>		251		349
<b>Gross profit</b>	5,690	7,965	20,743	26,187
<b>Operating expenses:</b>				
Research and development	738,865	979,089	2,031,727	3,078,730
Selling, general and administrative	649,764	623,130	2,417,406	2,087,930
Total operating expenses	1,388,629	1,602,219	4,449,133	5,166,660
<b>Loss from operations</b>	(1,382,939 )	(1,594,254 )	(4,428,390 )	(5,140,473 )
<b>Other income (expense):</b>				
Interest income	38,458	15,038	90,349	38,238
Interest expense	(47,571 )	(35,151 )	(131,829 )	(102,230 )
Amortization of note discount	(115,469 )	(115,469 )	(346,406 )	(346,407 )
Total other expense	(124,582 )	(135,582 )	(387,886 )	(410,399 )
<b>Net loss</b>	\$ (1,507,521 )	\$ (1,729,836 )	\$ (4,816,276 )	\$ (5,550,872 )
<b>Net loss per weighted average share, basic and diluted</b>	\$ (0.06 )	\$ (0.07 )	\$ (0.20)	\$ (0.24 )
<b>Weighted average number of common shares outstanding</b>	<b>23,689,490</b>	<b>23,530,154</b>	<b>23,649,365</b>	<b>23,451,930</b>

The accompanying notes are an integral part of these consolidated financial statements.

**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Unaudited)

	<b>For the Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2005</b>	<b>2004</b>
		<b>(As Restated)</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,816,276 )	\$ (5,550,872 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	249,077	90,224
Amortization of note discount	346,406	346,407
Changes in operating assets and liabilities:		
Accounts receivable	9,766	(3,393 )
Prepaid expenses and other current assets	(2,236 )	(58,679 )
Accounts payable	(1,891 )	492,710
Accrued expenses	(227,399 )	101,396
Deferred revenue	1,990,000	(12,000 )
Commitments for funded research and development projects	(73,578 )	494,726
Net cash used in operating activities	(2,526,131 )	(4,099,481 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of fixed assets	(47,327 )	(657,407 )
Increase in other assets	(108,098 )	(132,430 )
Net cash used in investing activities	(155,425 )	(789,837 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from investment by Alticor	2,196,832	5,016,688
Proceeds from exercises of warrants and stock options	239,510	615,446
Proceeds from employee stock purchase plan	21,436	24,129
Principal payments of capital lease obligations, net	(11,387 )	(19,408 )
Net cash provided by financing activities	2,446,391	5,636,855
Net (decrease) increase in cash and cash equivalents	(235,165 )	747,537
Cash and cash equivalents, beginning of period	4,528,425	4,759,453
<b>Cash and cash equivalents, end of period</b>	<b>\$ 4,293,260</b>	<b>\$ 5,506,990</b>
<b>Supplemental disclosures of cash flow information:</b>		
Cash paid for interest	\$ 131,829	\$ 102,230

The accompanying notes are an integral part of these consolidated financial statements.

**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

**Note 1. Basis of Presentation**

The accompanying unaudited interim consolidated financial statements include the accounts of Interleukin Genetics, Inc. and its wholly-owned subsidiary, Interleukin Genetics Laboratory Services, Inc., (collectively referred to as the Company or Interleukin ) as of September 30, 2005 and have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America for interim financial reporting and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and notes required by generally accepted accounting principles for complete financial statements. All intercompany accounts and transactions have been eliminated. These unaudited interim consolidated financial statements, which, in the opinion of management, reflect all adjustments (including normal recurring adjustments) necessary for a fair presentation, should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2004, as amended. Operating results for the three months and nine months ended September 30, 2005 are not necessarily indicative of the results that may be expected for any future interim period or for the entire fiscal year.

**Note 2. Restatement of Consolidated Financial Statements**

The accompanying consolidated financial statements for the three months and nine months ended September 30, 2004 have been restated to properly account for the transaction entered into with Alticor, Inc and its affiliates on March 5, 2003. For the purpose of clarity, in this document we will refer to Alticor and all of its wholly-owned subsidiaries, including Access Business Group, Pyxis Innovations, Inc. and Quixtar as Alticor .

In a private placement on March 5, 2003, the Company entered into a Stock Purchase Agreement with Alticor, pursuant to which Alticor purchased from the Company 5,000,000 shares of the Company's Series A Preferred Stock, \$0.001 per share, for \$7,000,000 in cash and \$2,000,000 in cash to be paid, if at all, upon the Company reaching a milestone pursuant to the terms of the Stock Purchase Agreement. The Series A Preferred Stock issued in the private placement was initially convertible into 28,157,683 shares of the Company's Common Stock at the purchaser's discretion. Pursuant to the terms of the Stock Purchase Agreement, Alticor agreed to refinance, in the form of convertible debt, certain of the Company's indebtedness in the form of previously issued promissory notes that were held by Alticor and certain individuals. This amounted to \$2,595,336 in debt refinanced and was initially convertible into 5,219,903 shares of the Company's Common Stock. Concurrent with the closing of the Stock Purchase Agreement, the Company entered into a research agreement with Alticor that would provide additional funding of \$5,000,000 to be paid quarterly over a two-year period.

In accordance with Emerging Issues Task Force (EITF) No. 01-1, *Accounting for Convertible Instruments Granted or Issued to a Nonemployee for Goods or Services or a Combination of Goods or Services and Cash* (EITF No. 01-1), the terms of both the agreement for goods or services provided and the convertible instrument should be evaluated to determine whether their separately stated pricing is equal to the fair value of the goods or services provided and the convertible instrument. If that is not the case, the terms of the respective transactions should be adjusted. The convertible instrument should be recognized at its fair value with a corresponding increase or decrease in the sales price of the goods or services.

**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**Note 2. Restatement of Consolidated Financial Statements (Continued)**

On March 5, 2003, the Company was obligated to issue up to 33,377,586 shares of its common stock underlying the convertible preferred stock and the convertible debt issued. Based on the last reported trade price of \$0.71 per common share of the Company's common stock on March 5, 2003, the convertible instruments had a fair value of \$23,698,086 on the date of issuance. Based on the fair value of the convertible instruments and the guidance provided by EITF 01-1, the Company will recognize the fair value of the convertible instruments, to the extent of proceeds received, with a corresponding decrease to the sales price of the goods and services provided. At March 5, 2003, the Company treated the \$5,000,000 committed research funding as an equity investment rather than revenue and any costs of performing the research services under the agreement will be classified as research and development expenses. Any subsequent proceeds that the Company will receive from Alticor that are linked to the March 2003 transaction, will be considered equity rather than revenue to the extent of the fair value of the convertible instruments at March 5, 2003. During 2003 and the nine months ended September 30, 2004, the Company received various purchase orders from Alticor valued at \$241,800 to conduct genotyping tests for research purposes. These purchase orders are deemed to be linked to the March 2003 transaction, and accordingly are treated as equity rather than revenue. The effect of this treatment resulted in an increase to net loss for the three months ended September 30, 2004 of \$1,391,850, or \$0.06 per common share, and \$2,682,450, or \$0.11 per common share, for the nine months ended September 30, 2004.

In accordance with EITF No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments* (EITF No. 00-27), the Company determined that the convertible preferred debt issued on March 5, 2003 contained a beneficial conversion feature. Based on the effective conversion price of the convertible debt of \$0.2875 (which was determined by allocating the proceeds received on March 5, 2003 of \$9,595,336 based on the relative fair value of the convertible securities issued, or \$8,094,727 to the convertible preferred stock and \$1,500,609 to the convertible debt) and the market value per share of \$0.71 at March 5, 2003, the intrinsic value was calculated to be \$2,205,522; however in accordance with EITF No. 00-27, the amount of the discount allocated to the beneficial conversion feature is limited to the amount of the proceeds allocated to the instrument. The beneficial conversion feature resulted in a discount of the convertible debt of \$1,500,609 at March 5, 2003. The amount of the discount allocated to the beneficial conversion feature of the convertible debt is amortized from the date of issuance to the earlier of maturity or the actual conversion date. Therefore, the Company charged \$77,618 and \$232,853 to amortization of note discount for the three months and nine month ended September 30, 2004, respectively, which resulted in an increase to net loss for the three months and nine months ended September 30, 2004 of \$77,618, or less than \$0.01 per common share, and \$232,853, or \$0.01 per common share, respectively.

In addition, the convertible debt has a stated interest rate of prime plus 1%. However, the promissory notes, which were refinanced with the convertible debt, originally had a stated interest rate of 15%. Therefore, the Company determined the fair value of the convertible debt, using an interest rate comparable to that of the refinanced promissory notes, at \$1,863,553. The resulting discount of \$731,783 is amortized from the date of issuance to the earlier of maturity or conversion date. Therefore, the Company charged \$37,851 and \$113,554 to amortization of note discount for the three months and nine months ended September 30, 2004, respectively, which resulted in an increase to net loss for the three months and nine months ended September 30, 2004 of \$37,851, or less than \$0.01 per common share, and \$113,554, or less than \$0.01 per common share, respectively.



**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**Note 2. Restatement of Consolidated Financial Statements (Continued)**

In connection with the research agreement with Alticor dated March 5, 2003, the Company is obligated to purchase two clinical databases. As of June 30, 2004, the Company determined that this obligation met the criteria of Statement of Financial Accounting Standards (SFAS) No. 5, *Accounting for Contingencies*, and estimated the cost of these two databases at \$450,000. Accordingly, the Company recorded a liability and charged research and development expenses of \$450,000 at that time, which resulted in an increase to net loss for the nine months ended September 30, 2004 of \$300,000, or \$0.01 per common share.

The following table presents the financial statement adjustments on the Company's previously reported consolidated statement of operations for the three months and nine months ended September 30, 2004.

	<b>Three Months Ended September 30, 2004</b>		<b>Nine Months Ended September 30, 2004</b>	
	<b>(As Reported)</b>	<b>(As Restated)</b>	<b>(As Reported)</b>	<b>(As Restated)</b>
<b>Revenue</b>	\$ 1,400,066	\$ 8,216	\$ 2,708,986	\$ 26,536
<b>Cost of revenue</b>	829,188	251	1,775,833	349
<b>Gross profit</b>	570,878	7,965	933,153	26,187
<b>Operating expenses:</b>				
Research and development	256,083	979,089	991,843	3,078,730
Selling, general and administrative	667,199	623,130	2,099,333	2,087,930
Total operating expenses	923,282	1,602,219	3,091,176	5,166,660
<b>Loss from operations</b>	(352,404 )	(1,594,254 )	(2,158,023 )	(5,140,473 )
<b>Other income (expense):</b>				
Interest income	15,038	15,038	38,238	38,238
Interest expense	(35,151 )	(35,151 )	(102,230 )	(102,230 )
Amortization of note discount		(115,469 )		(346,407 )
Total other expense	(20,113 )	(135,582 )	(63,992 )	(410,399 )
<b>Net loss</b>	\$ (372,517 )	\$ (1,729,836 )	\$ (2,222,015 )	\$ (5,550,872 )
<b>Net loss per weighted average share, basic and diluted</b>	\$ (0.02 )	\$ (0.07 )	\$ (0.09 )	\$ (0.24 )
<b>Weighted average number of common shares, basic and diluted</b>	<b>23,530,154</b>	<b>23,530,154</b>	<b>23,451,930</b>	<b>23,451,930</b>

**Note 3. Significant Accounting Policies**

*Management Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenue and expenses during the reported periods. Actual results could differ from those estimates. The Company's most critical accounting policies are in the areas of its strategic alliance with Alticor, stock-based compensation, income taxes, intellectual

**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**Note 3. Significant Accounting Policies (Continued)**

property, beneficial conversion feature of convertible instruments and the fair value of the convertible debt. These critical accounting policies are more fully discussed in these notes to consolidated financial statements.

*Strategic Alliance with Alticor*

In a private placement on March 5, 2003, the Company entered into a Stock Purchase Agreement with Alticor, pursuant to which Alticor purchased from the Company 5,000,000 shares of the Company's Series A Preferred Stock, \$0.001 per share, for \$7,000,000 in cash and \$2,000,000 in cash to be paid, if at all, upon the Company reaching a milestone pursuant to the terms of the Stock Purchase Agreement. The Series A Preferred Stock issued in the private placement was initially convertible into 28,157,683 shares of the Company's Common Stock at the purchaser's discretion. Pursuant to the terms of the Stock Purchase Agreement, Alticor agreed to refinance, in the form of convertible debt, certain of the Company's indebtedness in the form of previously issued promissory notes that were held by Alticor and certain individuals. This amounted to \$2,595,336 in debt refinanced and was initially convertible into 5,219,903 shares of the Company's Common Stock. Concurrent with the closing of the Stock Purchase Agreement, the Company entered into a research agreement with Alticor that would provide additional funding of \$5,000,000 to be paid quarterly over a two-year period.

In accordance with EITF No. 01-1, the terms of both the agreement for goods or services provided and the convertible instrument should be evaluated to determine whether their separately stated pricing is equal to the fair value of the goods or services provided and the convertible instrument. If that is not the case, the terms of the respective transactions should be adjusted. The convertible instrument should be recognized at its fair value with a corresponding increase or decrease in the sales price of the goods or services.

On March 5, 2003, the Company was obligated to issue up to 33,377,586 shares of its common stock underlying the convertible preferred stock and the convertible debt issued. Based on the last reported trade price of \$0.71 per common share of the Company's common stock on March 5, 2003, the convertible instruments had a fair value of \$23,698,086 on the date of issuance. Based on the fair value of the convertible instruments and the guidance provided by EITF 01-1, the Company will recognize the fair value of the convertible instruments, to the extent of proceeds received, with a corresponding decrease to the sales price of the goods and services provided. At March 5, 2003, the Company treated the \$5,000,000 committed research funding as an equity investment rather than revenue and any costs of performing the research services under the agreement were classified as research and development expenses. Any subsequent proceeds that the Company will receive from Alticor that are linked to the March 2003 transaction, will be considered equity rather than revenue to the extent of the fair value of the convertible instruments at March 5, 2003. In June 2004, the Company entered into another research agreement with Alticor for potential funding up to \$2,200,000 and in March 2005, the Company entered into two more agreements to provide additional funding of \$5,057,651 over two years beginning April 1, 2005. In addition, since March 5, 2003, the Company has received various purchase orders from Alticor valued at \$501,800 to conduct genotyping test for research purposes. These purchase orders, together with the research agreements entered into in June 2004 and March 2005, are deemed to be linked to the March 2003 transaction, and accordingly are treated as equity rather than revenue. As of September 30, 2005, proceeds

**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**Note 3. Significant Accounting Policies (Continued)**

received from Alticor which were recorded as consideration for the fair value of the convertible instruments issued in March 2003, amounted to \$20,455,256. As of September 30, 2005, there was \$3,242,830 of fair value of the convertible instruments that has not been recorded as equity.

*Stock-based Compensation*

Stock options issued to employees under the Company's stock option and stock purchase plans are accounted for under Accounting Principles Board Opinion No. 25 (APB No. 25), *Accounting for Stock Issued to Employees*. All stock-based awards to non-employees are accounted for at their fair value in accordance with Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123), and EITF Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees*.

The Company applies the disclosure-only alternative of SFAS No. 123, which defines a fair-value-based method of accounting for employee stock options or similar equity instruments. Under the fair-value-based method, compensation cost is measured at the grant date based on the value of the award and is recognized over the service period of the award, which is usually the vesting period. However, SFAS No. 123 also allows entities to continue to measure compensation costs for employee stock compensation plans using the intrinsic value method of accounting prescribed in APB No. 25. The Company has elected to continue to follow the accounting prescribed by APB No. 25 and has made the required disclosures prescribed by SFAS No. 123.

Had compensation cost for the Company's employee stock awards been determined consistent with SFAS No. 123, the Company's net loss applicable to common stock and net loss per share would have been as follows:

	<b>Three Months Ended September 30, 2005</b>	<b>2004 (As Restated)</b>	<b>Nine Months Ended September 30, 2005</b>	<b>2004 (As Restated)</b>
Net loss attributable to common stockholders:				
As reported	\$ (1,507,521 )	\$ (1,729,836 )	\$ (4,816,276 )	\$ (5,550,072 )
Stock-based employee compensation	(150,121 )	(125,940 )	(439,195 )	(497,399 )
Pro Forma	\$ (1,657,642 )	\$ (1,855,776 )	\$ (5,255,471 )	\$ (6,047,471 )
Basic and diluted net loss per common share:				
As reported	\$ (0.06 )	\$ (0.07 )	\$ (0.20 )	\$ (0.24 )
Pro Forma	\$ (0.07 )	\$ (0.08 )	\$ (0.22 )	\$ (0.26 )

**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**Note 3. Significant Accounting Policies (Continued)**

The fair value of the options was estimated at the date of grant using the Black-Scholes option valuation model with the weighted average assumptions listed in the table below:

	2005		2004	
Risk free interest rate	5.00	%	4.00	%
Expected life	7 years		7 years	
Expected volatility	70	%	80	%

Using these assumptions, the weighted average grant date fair value of options granted in 2005 and 2004 was \$2.18, and \$3.24, respectively.

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options. The Company's employee stock options have characteristics significantly different from those of traded options such as extremely limited transferability and, in most cases, vesting restrictions. In addition, the assumptions used in option valuation models are based upon historical averages that may not predict future results, particularly the expected stock price volatility of the underlying stock. Because changes in these input assumptions can materially affect the fair value estimate, in management's opinion, existing valuation models do not provide a reliable, single measure of the fair value of the Company's employee stock options.

*Income Taxes*

The preparation of its consolidated financial statements requires the Company to estimate its income taxes in each of the jurisdictions in which it operates, including those outside of the United States, which may be subject to certain risks that ordinarily would not be expected in the United States. The income tax accounting process involves estimating its actual current exposure together with assessing temporary differences resulting from different treatment of items, such as deferred revenue, for tax and accounting purposes. These differences result in the recognition of deferred tax assets and liabilities. The Company must then record a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be realized.

Significant management judgment is required in determining the Company's provision for income taxes, its deferred tax assets and liabilities and any valuation allowance recorded against its deferred tax assets. The Company has recorded a full valuation allowance against its deferred tax assets of \$15.8 million as of September 30, 2005, due to uncertainties related to its ability to utilize these assets. The valuation allowance is based on management's estimate of future taxable income by jurisdiction in which the Company operates and the period over which the deferred tax assets will be recoverable. In the event that actual results differ from these estimates or management adjusts these estimates in future periods, the Company may need to adjust its valuation allowance which could materially impact the financial position and results of operations.

*Intellectual Property*

Prior to March 2003, costs incurred in connection with obtaining patent protection for intellectual property were expensed as incurred due to the possibility that the Company would never be able to derive

**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**Note 3. Significant Accounting Policies (Continued)**

any benefits from its patents. As of September 30, 2005, the Company has exclusive rights (subject to rights granted to Alticor within the fields of dermagenomics and nutrigenomics) in seventeen issued U.S. patents and has a number of U.S. patents applications pending. The Company has also been granted a number of corresponding foreign patents and a number of foreign counterparts of its U.S. patents and patent applications pending. Since inception the Company has expensed approximately \$ 3.0 million in the effort to obtain patent protection for its intellectual property. Due to the alliance with Alticor that was entered into on March 5, 2003, the Company began capitalizing certain costs of obtaining patent protection for which the prospect of deriving benefits had become more certain. As of September 30, 2005 and December 31, 2004, the Company has capitalized \$421,069 and \$311,466, respectively, in patent costs and is included in other assets in the accompanying consolidated balance sheets. The Company amortizes these patents over the shorter of the life of the patent or ten years, their expected useful life. Accumulated amortization of capitalized patent costs was \$53,233 and \$28,410 at September 30, 2005 and December 31, 2004, respectively.

*Beneficial Conversion Feature of Convertible Instruments*

Based on EITF No. 00-27, the Company determined that the convertible debt issued on March 5, 2003 contained a beneficial conversion feature. Based on the effective conversion price (which was determined by allocating the proceeds received on March 5, 2003 of \$9,595,336 based on the relative fair value of the convertible securities issued, or \$8,094,727 to the convertible preferred stock and \$1,500,609 to the convertible debt) of the convertible debt of \$0.2875 and the market value per share of \$0.71 at March 5, 2003, the intrinsic value was calculated to be \$2,205,522; however in accordance with EITF NO. 00-27, the amount of the discount allocated to the beneficial conversion feature is limited to the amount of the proceeds allocated to the instrument. The beneficial conversion feature resulted in a discount on the convertible debt of \$1,500,609 at March 5, 2003. The amount of the discount allocated to the beneficial conversion feature of the convertible debt is amortized from the date of issuance to the earlier of maturity or the actual conversion date. Therefore, the Company charged \$77,618 to amortization of note discount for the three months ended September 30, 2005 and 2004 and \$232,853 for the nine months ended September 30, 2005 and 2004. As of September 30, 2005, the unamortized discount associated with the beneficial conversion feature was \$698,560.

*Fair Value of Convertible Debt*

The convertible debt issued in March 2003 has a stated interest rate of prime plus 1%. However, the promissory notes, which were refinanced with the convertible debt, originally had a stated interest rate of 15%. Therefore, the Company determined the fair value of the convertible debt, using an interest rate comparable to that of the refinanced promissory notes, at \$1,863,553. The resulting discount of \$731,783 is amortized from the date of issuance to the earlier of maturity or conversion date. Therefore, the Company charged \$37,851 to amortization of note discount for the three months ended September 30, 2005 and 2004 and \$113,554 for the nine months ended September 30, 2005 and 2004. As of September 30, 2005, the unamortized discount associated with the below market interest rate was \$340,657.

**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**Note 3. Significant Accounting Policies (Continued)**

*Basic and Diluted Net Loss per Common Share*

The Company applies SFAS No. 128, *Earnings per Share* (SFAS No. 128), which establishes standards for computing and presenting earnings per share. Basic and diluted net loss per share was determined by dividing net loss applicable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is the same as basic net loss per share for all the periods presented, as the effect of the potential common stock equivalents is anti-dilutive due to the net loss in each period. Potential common stock excluded from the calculation of diluted net loss per share consists of stock options, warrants, preferred stock and convertible debt as described in the table below:

	<b>September 30,</b>	
	<b>2005</b>	<b>2004</b>
Options outstanding	2,911,315	2,855,167
Warrants outstanding	525,000	525,000
Preferred stock	28,160,200	28,160,200
Convertible debt	4,060,288	4,060,288
<b>Total</b>	<b>35,656,803</b>	<b>35,600,655</b>

*Reclassifications*

Certain prior year balances have been reclassified to conform to current year presentation.

*Recent Accounting Pronouncements*

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (Revised 2004), *Share-Based Payment* (SFAS No. 123R). The statement replaces SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees*. SFAS No. 123R addresses all forms of share-based payment ( SBP ) awards, including shares issued under employee stock purchase plans, stock options, restricted stock and stock appreciation rights. SFAS No. 123R will require the Company to expense SBP awards with compensation cost for SBP transactions measured at fair value. SFAS No. 123R applies to new equity awards and to equity awards modified, repurchased or canceled after the effective date. Additionally, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the effective date shall be recognized as the requisite service is rendered on or after the effective date. The compensation cost for that portion of awards shall be based on the grant-date fair value of those awards as calculated from the pro forma disclosures under SFAS No. 123. Additionally, common stock purchased pursuant to stock options granted under the Company's employee stock purchase plan will be expensed based upon the fair market value of the stock option. SFAS No. 123R requires the Company to adopt the new accounting provisions beginning in 2006. The adoption of SFAS No. 123R will have a material impact on the Company's results of operations. Future results will be impacted by the number and value of additional equity awards as well as the value of existing unvested equity awards.

In June 2005, FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* (SFAS No. 154). This statement replaces APB Opinion No. 20, *Accounting Changes*, and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. The statement applies to all voluntary changes in accounting for



**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**Note 3. Significant Accounting Policies (Continued)**

reporting of changes in accounting principles. SFAS No. 154 requires retrospective application to prior periods financial statements of a voluntary change in accounting principles unless it is not practical to do so. APB No. 20 previously required that most voluntary changes in accounting principles be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Earlier application is permitted for accounting changes and corrections of errors made occurring in fiscal years beginning after May 31, 2005. The adoption of SFAS No. 154 will not have a material impact on the Company's financial position or results of operations.

**Note 4. Strategic Alliance with Alticor, Inc.**

On March 5, 2003, the Company entered into a broad strategic alliance with Alticor to develop and market personalized nutritional and skin care products. The alliance utilizes Interleukin Genetics' intellectual property and expertise in genomics to develop personalized consumer products. Alticor has a long history of manufacturing and distributing high quality nutritional supplements and skin care products to a worldwide market.

The alliance initially included an equity investment, a multi-year research and development agreement, a licensing agreement with royalties on marketed products, the deferment of outstanding loan repayment and the refinancing of bridge financing obligations. The major elements of the initial alliance were:

- The purchase by Alticor of \$7,000,000 of equity in the form of 5,000,000 shares of Series A Preferred Stock for \$1.40 per share. These were convertible into 28,157,683 shares of common stock at a stated conversion price equal to \$0.2486 per share. On March 11, 2004, upon achievement of a defined milestone, Alticor contributed an additional \$2,000,000 to the Company, for no additional shares of Series A Preferred Stock, for a total equity funding of \$9,000,000 and a new stated conversion price of \$0.3196 per share, or 28,160,200 shares of common stock.
- The right of the Series A Preferred stockholders to nominate and elect four directors to a five person board.
- A research and development agreement (Research Agreement I) providing the Company with funding of \$5,000,000, payable over the twenty-four month period from April 2003 through March 2005, to conduct certain research projects with a royalty on resulting products.
- Credit facilities in favor of Interleukin, as follows:
  - \$1,500,000 working capital credit line to initiate selected research agreements with third party entities approved by the board of directors of Interleukin;
  - \$2,000,000 refinancing of notes previously held by Alticor, extending the maturity date and reducing the interest rate; and
  - \$595,336 refinancing on July 1, 2003 of bridge financing notes previously held by third parties, extending the maturity date and reducing the interest rate.



**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**Note 4. Strategic Alliance with Alticor, Inc. (Continued)**

As of September 30, 2005, there was \$2,595,336 outstanding under the terms of these credit facilities. The credit facilities will mature in December 2007, bear interest at 1% over the prime rate (7.75 % at September 30, 2005), are collateralized by a security interest in the Company's intellectual property, (except intellectual property relating to periodontal disease and sepsis) and are convertible at the election of Alticor into 4,060,288 shares of common stock at a stated conversion price equal to \$0.6392 per share.

On June 17, 2004, the Company entered into another research agreement (Research Agreement II) with Alticor, valued at \$2,200,000 to conduct research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight. During the first phase of the agreement, the Company received \$1,380,000 in research funding over a period of six months beginning on July 1, 2004. If Alticor determines, in its sole discretion, that it has a reasonable likelihood of commercializing weight management nutritional products, the Company will be eligible to receive, during the second phase of the agreement, an additional \$820,000 in funding over a six-month period.

On March 5, 2005, the Company entered into an agreement with Alticor to expand the research being performed under Research Agreement I (Research Agreement III) to provide additional funding of \$2.7 million over the two years beginning April 1, 2005. Also in March 2005, the Company entered into an additional research agreement (Research Agreement IV) with Alticor for exploratory research valued at \$2.3 million over a two-year period commencing April 1, 2005. These research agreements are expected to provide the Company with a total of \$5.0 million during the two-year period ending March 2007.

In addition, in April 2005, Alticor paid the Company, \$2.0 million as an advance payment for genetic risk assessment tests to be processed under the terms of a distribution agreement. This amount is included in deferred revenue as of September 30, 2005 on the accompanying balance sheet and will be recognized as revenue as the tests are processed. These tests are expected to be processed beginning in the first quarter of 2006. Further, Alticor agreed to extend the loan period of the \$1.5 million working capital credit line through March 5, 2007.

**Note 5. Debt**

On March 5, 2003 as part of its strategic alliance with Alticor, the Company was granted credit facilities as follows:

- \$1,500,000 working capital credit line to initiate selected research agreements with third party entities approved by the board of directors of Interleukin;
- \$2,000,000 refinancing of notes previously held by Alticor, extending the maturity date and reducing the interest rate; and
- \$595,336 refinancing on July 1, 2003 of bridge financing notes previously held by third parties, extending the maturity date and reducing the interest rate.

As of September 30, 2005 there was \$2,595,336 outstanding under the terms of these credit facilities. The credit facilities will mature in December 2007, bear interest at 1% over the prime rate (7.75 % at September 30, 2005), are collateralized by a security interest in the Company's intellectual property

**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**Note 5. Debt (Continued)**

(except intellectual property related to periodontal disease and sepsis), and are convertible at the election of Alticor into shares of common stock at a conversion price equal to \$0.6392 per share.

**Note 6. Capital Stock**

*Authorized Common and Preferred Stock*

At September 30, 2005, the Company had authorized 6,000,000 shares of Series A Preferred stock of which 5,000,000 shares were issued and outstanding. At September 30, 2005, the Company had authorized 75,000,000 shares of \$0.001 par value common stock of which 61,960,825 shares were outstanding or reserved for issuance. Of those, 23,763,399 shares were common and outstanding, 28,160,200 shares were reserved for the conversion of the Series A Preferred to common stock, 4,060,288 shares were reserved for the conversion of approximately \$2.6 million of debt, 4,996,804 shares were reserved for the exercise of authorized and outstanding stock options, 525,000 shares were reserved for the exercise of outstanding warrants to purchase common stock and 455,134 shares were reserved for the exercise of rights held under the Employee Stock Purchase Plan.

*Series A Preferred Stock*

On March 5, 2003, the Company entered into a Purchase Agreement with Alticor, pursuant to which Alticor purchased from the Company Series A Preferred Stock for \$7,000,000 in cash on that date, and an additional \$2,000,000 in cash that was paid, as a result of the Company achieving a certain milestone, on March 11, 2004.

The Series A Preferred Stock accrues dividends at the rate of 8% of the original purchase price per year, payable only when, as and if declared by the Board of Directors and are non-cumulative. To date, no dividends have been declared on these shares. If the Company declares a distribution, with certain exceptions, payable in securities of other persons, evidences of indebtedness issued by us or other persons, assets (excluding cash dividends) or options or rights to purchase any such securities or evidences of indebtedness, then, in each such case the holders of the Series A Preferred Stock shall be entitled to a proportionate share of any such distribution as though the holders of the Series A Preferred Stock were the holders of the number of shares of our Common Stock into which their respective shares of Series A Preferred Stock are convertible as of the record date fixed for the determination of the holders of our Common Stock entitled to receive such distribution.

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of the Series A Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of the Company's assets or surplus funds to the holders of its Common Stock by reason of their ownership thereof, the amount of two times the then-effective purchase price per share, as adjusted for any stock dividends, combinations or splits with respect to such shares, plus all declared but unpaid dividends on such share for each share of Series A Preferred Stock then held by them. The liquidation preference at September 30, 2005 was \$18,000,000. After receiving this amount, the holders of the Series A Preferred Stock shall participate on an as-converted basis with the holders of common stock in any of the remaining assets.

**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**Note 6. Capital Stock (Continued)**

Each share of Series A Preferred Stock is convertible at any time at the option of the holder into a number of shares of the Company's common stock determined by dividing the then-effective purchase price (\$1.80, and subject to further adjustment) by the conversion price in effect on the date the certificate is surrendered for conversion. As of September 30, 2005, the Series A Preferred Stock is convertible into 28,160,200 shares of Common Stock reflecting a conversion price of \$.3196 per share.

Each holder of Series A Preferred Stock is entitled to vote its shares of Series A Preferred Stock on an as-converted basis with the holders of Common Stock as a single class on all matters submitted to a vote of the stockholders, except as otherwise required by applicable law. This means that each share of Series A Preferred Stock will be entitled to a number of votes equal to the number of shares of Common Stock into which it is convertible on the applicable record date.

**Note 7. Commitments and Contingencies**

*Operating Leases*

The Company leases its office and laboratory space under a non-cancelable operating lease expiring March 2009. Future minimum lease commitments under this lease at September 30, 2005 are \$1,529,514.

*Acquisition of Data Bases*

In connection with the research agreement with Alticor dated March 5, 2003, the Company is obligated to purchase two clinical databases. At June 30, 2004, the Company determined that this obligation met the criteria of SFAS No. 5, *Accounting for Contingencies*, and estimated the cost of these two databases at \$450,000. Accordingly, the Company recorded a liability and charged research and development expenses of \$450,000 at that time. As of September 30, 2005, the Company had negotiated the acquisition of the first of the two databases. The Company believes that the acquisition of the databases will not exceed the amount that the Company has estimated, however actual amounts could differ.

*Sponsored Research Agreements*

In connection with the research agreement with Alticor dated June 17, 2004, the Company entered into a sponsored research agreement with Tufts University to conduct a clinical study. The sponsored research agreement is for an amount not to exceed \$662,000 and is payable upon achievement of certain milestones. As of September 30, 2005, Tufts University had achieved two of the four milestone payments valued at \$350,000. The remaining commitment on this agreement is \$312,000. As, and if, Tufts University completes the other milestones associated with this sponsored research agreement, the Company will record these costs as research and development expenses.

**Note 8. Segment Information and Foreign Currency Risk**

The Company follows SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information* (SFAS No. 131) which establishes standards for reporting information about operating segments in annual and interim financial statements, and requires that companies report financial and descriptive information about its reportable segments based on a management approach. SFAS No. 131

**INTERLEUKIN GENETICS, INC. AND SUBSIDIARY**  
**NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
**(Unaudited)**

**Note 8. Segment Information and Foreign Currency Risk (Continued)**

also establishes standards for related disclosures about products and services, geographic areas and major customers. In applying the requirements of this statement, each of the Company's geographic areas described below was determined to be an operating segment as defined by the statement, but have been aggregated as allowed by the statement for reporting purposes. As a result, the Company continues to have one reportable segment, which is the development of genetic risk assessment tests and therapeutic targets for common diseases.

The Company has no operations outside of the United States. For the three months and nine months ended September 30, 2005 and 2004, the Company had minimal royalty income derived from distributors outside the United States, minimal expenses derived from research partners outside the United States and minimal assets outside of the United States. The Company does not believe this risk is material and does not use derivative financial instruments to manage foreign currency fluctuation risk.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

This report on Form 10-Q and the documents incorporated by reference within this document contain certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act. Statements contained in this report that are not statements of historical fact may be deemed to be forward-looking statements. Words or phrases such as "will likely result", "expect", "will continue", "anticipate", "estimate", "intend", "plan", "project", "outlook", or similar expressions are intended to identify forward-looking statements. Forward-looking statements address or may address the following subjects:

- The sufficiency of our current cash resources together with additional research agreements, anticipated revenue from product launches and other arrangements to fund operations through mid-2006;
- Our expectation that we will receive at least \$5.0 million in funding over the twenty-four month period ending March 2007 from an affiliate of Alticor under the terms of various research agreements with this affiliate;
- Our expectation that we will receive royalty payments and/or genetic test processing revenue under the terms of a license agreement and a distribution agreement with Alticor;
- Our expectation that we may sign additional research agreements with Alticor, or other third parties;
- Our expectation of the benefits that will result from the ongoing research programs that outside parties are conducting on our behalf;
- Any expectation we may have regarding the success of developing products, the timing of releasing products for sale or the success of these products when they are released;
- Any expectation we may have of attracting business partners to assist in developing, marketing or distribution of our products;
- Any expectation that certain healthcare related trends will emerge or continue that will support our business model;
- Our expectation that our total research and development costs will be between approximately \$3.0 million and \$3.5 million for the year ended December 31, 2005 and between approximately \$2.5 million and \$3.0 million for the six months ended June 30, 2006;
- Our expectation that we might derive benefit from our patented intellectual property; and
- Our expectation that we will continue to experience losses until our genetic testing revenue grows substantially from current levels.

Actual results may vary materially from those expressed in forward-looking statements. Factors that could cause actual results to differ from expectations include but are not limited to; risks related to market acceptance of genetic risk assessment tests in general and our products in particular, risks related to technology and product obsolescence, delays in development of products, dependence on third parties, our ability to fund operations through mid-2006, competitive risks and those risks set forth within the section titled "Certain Factors That May Affect Future Results of Operations or the Market for Our Common Stock" beginning on page 23 within this report. We cannot be certain that our results will not be adversely affected by one or more of these factors or by other factors not currently anticipated. All information set forth in this Form 10-Q is as of the date of this Form 10-Q. Unless required by law, we accept no responsibility to update this information.

## General Overview

We are in the business of personalized health. We are developing tests and products that can help individuals improve and maintain their health through preventive measures. We plan to develop the following types of products: 1) genetic risk assessment products, 2) preventive nutritional products (foods and nutritionals developed to prevent disease onset), and 3) personalized therapeutics that treat an individual with existing disease and use genetic information to expedite drug development and to target the drug use to individuals most likely to respond favorably. We will use our intellectual property and expertise to develop products or acquire additional intellectual property that can be leveraged, through collaboration with partners, to address unmet market needs. We are currently developing a number of genetic risk assessment tests to be distributed by Alticor in their multi-level marketing channel. The market launch for the first of such tests is expected to occur in the first quarter of 2006.

Our current commercial strategy is to partner with companies that have sales and marketing capabilities and products or services that complement our own products. We currently have no plans to develop our own sales force; we plan to rely on our strategic partners to promote and distribute our products. The first of these strategic partnerships is the partnership we have with Alticor.

Our revenue model consists of: 1) charging a fee for processing a genetic risk assessment test and generating a personalized risk assessment report; and 2) receiving a royalty from sales of products developed with a partner, or profit sharing from product sales. Furthermore, we plan to collaborate with other companies in the research and development of products. In these collaborations, we expect to receive a certain amount of research funding from the partner covering labor, material, overhead and a small amount of profit. Our first such collaboration is with Alticor for the development of personalized nutritional and skincare products.

On March 5, 2003, we entered into a broad strategic alliance Alticor to develop and market personalized nutritional and skin care products. The alliance utilizes our intellectual property and expertise in genomics to develop personalized consumer products. Alticor has a long history of manufacturing and distributing high quality nutritional supplements and skin care products to a worldwide market through the multi-level marketing channel.

We are devoting most of our resources to the support of the strategic collaboration with Alticor which includes the development of our genetic risk assessment tests to be sold in combination with Alticor's products. A portion of our resources is also devoted to the development of a new product for the periodontal market. Additionally, we expect to continue incurring losses as we continue research and development efforts in the development of new tests and new products.

The alliance has included an equity investment, multi-year research and development agreements, a licensing agreement with royalties on marketed products, the deferment of outstanding loan repayment and the refinancing of bridge financing obligations. The financial elements of the alliance are described in greater detail within the Liquidity and Capital Resources section beginning on page 22.

Sufficiency of working capital remains our greatest challenge. The amount of cash generated from research collaborations with Alticor is not adequate to fund our operations, thus, resulting in an annual cash burn. The situation is, however, improving as discussed in the Liquidity and Capital Resources section beginning on page 22. Our current cash resources, together with additional research agreements, anticipated revenue from product launches, and other arrangements are adequate to fund operations through mid-2006.

## Critical Accounting Policies

Our significant accounting policies are described in Note 3 to the consolidated financial statements included in this report and were discussed in our Annual Report on Form 10-K for the year ended

December 31, 2004, as amended. We believe our most critical accounting policies are in the areas of our strategic alliance with Alticor, stock-based compensation and income taxes. We do not include the value of stock options issued to employees or our Directors as an expense. Had we expensed our stock-based compensation using the Black-Scholes option valuation model described below, our losses would have increased by \$150,000 (or less than \$0.01 per common share) and \$126,000 (or less than \$0.01 per common share) for the three months ended September 30, 2005 and 2004, respectively, and by \$439,000 (or \$0.02 per common share) and \$497,000 (or \$0.03 per common share) for the nine months ended September 30, 2005 and 2004, respectively.

## Results of Operations

### *Three Months Ended September 30, 2005 Compared to Three Months Ended September 30, 2004*

Revenue for the three months ended September 30, 2005 was \$6,000 compared to \$8,000 for the three months ended September 30, 2004, a decrease of \$2,000 or 31%. Royalties on PST® sales were \$1,000 (35 tests) and \$4,000 (359 tests) for 2005 and 2004, respectively. Licensing revenue was \$2,000 and \$4,000 for 2005 and 2004, respectively. For the three months ended September 30, 2005, revenue included \$3,000 from genotyping tests processed in our commercial laboratory.

Research and development expenses were \$739,000 for the three months ended September 30, 2005 compared to \$979,000 for the three months ended September 30, 2004, a decrease of \$240,000 or 25%. Funded research and development expenses were \$380,000 for the three months ended September 30, 2005 compared to \$667,000 for the three months ended September 30, 2004, a decrease of \$287,000 or 43%. Funded research and development expenses are direct costs incurred in connection with the research and development projects we are currently collaborating on with Alticor. In March 2003, we entered into a research agreement with Alticor to develop genetic tests and software to assess personalized risk and develop and use screening technologies to validate the effectiveness of the nutrigenomic consumables Alticor is developing. Additionally, we will play a key role in enhancing and maintaining scientific credibility in academic and medical communities. After our initial focus in developing products in the United States and Canada, we expect that we will expand our focus to include developing nutrigenomic products for sale overseas and developing products in the United States and overseas in other areas of wellness and skin care. In March 2005, we entered into two new agreements with Alticor to continue the research being performed. Direct expenses associated with these agreements were \$280,000 and \$327,000 for the three months ended September 30, 2005 and 2004, respectively. In June 2004, we entered into another research agreement with Alticor to conduct research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight. Direct expenses associated with this agreement were \$100,000 and \$311,000 for the three months ended September 30, 2005 and 2004, respectively. In addition, during 2004, we conducted genotyping tests for Alticor for research purposes. The costs associated with these tests were \$29,000 for the three months ended September 30, 2004. We believe that these reductions in funded research and development expenses are largely due to timing. Other research and development expenses, including overhead cost associated with research and development activities, were \$359,000 for the three months ended September 30, 2005 compared to \$312,000 for the three months ended September 30, 2004, an increase of \$46,000 or 15%. The increase is primarily the result of the hiring of the Chief Medical Officer in July 2005.

Selling, general and administrative expenses were \$650,000 for the three months ended September 30, 2005 compared to \$623,000 for the three months ended September 30, 2004, an increase of \$27,000 or 4%. Selling, general and administrative expenses for the three months ended September 30, 2005 include \$51,000 for compliance with Section 404 of the Sarbanes-Oxley Act of 2002 for fiscal year 2005. There were no costs incurred during the three months ended September 30, 2004 for compliance with Section 404 of the Sarbanes-Oxley Act of 2002. These expenses were offset in part by reductions in corporate overhead.

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Interest income was \$38,000 for the three months ended September 30, 2005 compared to \$15,000 for the same period in 2004. The increase is primarily the result of an increase in the cash and cash equivalents and an increase in the interest rate. Interest expense of \$48,000 was incurred during the three months ended September 30, 2005 compared to \$35,000 for the same period in 2004. The increase is primarily due to the increase in the prime rate over the two periods from 4.25% in 2004 to 6.25% in 2005.

We recorded amortization of note discount of \$115,000 for each of the three months ended September 30, 2005 and 2004. Of the \$115,000 expense, \$78,000 is due to the amortization of the \$1.5 million of discount resulting from the beneficial conversion feature of the convertible debt issued in March 2003 and \$37,000 is due to the amortization of the \$732,000 of discount associated with the below market stated interest rate.

### *Nine Months Ended September 30, 2005 Compared to Nine Months Ended September 30, 2004*

Revenue for the nine months ended September 30, 2005 was \$21,000 compared to \$27,000 for the nine months ended September 30, 2004, a decrease of \$6,000 or 22%. Royalties on PST® sales were \$8,000 (592 tests) and \$14,000 (1,424 tests) for 2005 and 2004, respectively. Licensing revenue was \$10,000 and \$12,000 for 2005 and 2004, respectively. For the nine months ended September 30, 2005, revenue included \$3,000 from genotyping tests processed in our commercial laboratory.

Research and development expenses were \$2.0 million for the nine months ended September 30, 2005 compared to \$3.1 million for the nine months ended September 30, 2004, a decrease of \$1.0 million or 34%. Funded research and development expenses were \$1.0 million for the nine months ended September 30, 2005 compared to \$2.0 million for the nine months ended September 30, 2004, a decrease of \$1.0 million or 50%. Funded research and development expenses are direct costs incurred in connection with the research and development projects we are currently collaborating on with Alticor. In March 2003, we entered into a research agreement with Alticor to develop genetic tests and software to assess personalized risk and develop and use screening technologies to validate the effectiveness of the nutrigenomic consumables Alticor is developing. Additionally, we will play a key role in enhancing and maintaining scientific credibility in academic and medical communities. After our initial focus in developing products in the United States and Canada, we expect that we will expand our focus to include developing nutrigenomic products for sale overseas and developing products in the United States and overseas in other areas of wellness and skin care. In March 2005, we entered into two new agreements with Alticor to continue the research being performed. Direct expenses associated with these agreements were \$747,000 and \$1.6 million for the nine months ended September 30, 2005 and 2004, respectively. In June 2004, we entered into another research agreement with Alticor to conduct research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight. Direct expenses associated with this agreement were \$189,000 and \$311,000 for the nine months ended September 30, 2005 and 2004, respectively. In addition, during 2005 and 2004, we conducted genotyping tests for Alticor for research purposes. The costs associated with these tests were \$66,000 for the nine months ended September 30, 2005 and \$45,000 for the same period in 2004. We believe that these reductions in funded research and development expenses are largely due to timing. Other research and development expenses, including overhead costs associated with research and development activities, were \$1.0 million for the nine months ended September 30, 2005 compared to \$1.1 million for the nine months ended September 30, 2004, a decrease of \$61,000 or 6%. The decrease is primarily the result of temporary reductions in labor and overhead partially offset by the hiring of the Chief Medical Officer in July 2005.

Selling, general and administrative expenses were \$2.4 million for the nine months ended September 30, 2005 compared to \$2.1 million for the nine months ended September 30, 2004, an increase of \$329,000 or 16%. Selling, general and administrative expenses for the nine months ended September 30, 2005 include \$247,000 for compliance with Section 404 of the Sarbanes-Oxley Act of 2002 for fiscal year 2004 and \$169,000 for fiscal year 2005. There were no costs incurred during the nine months ended



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September 30, 2004 for compliance with Section 404 of the Sarbanes-Oxley Act of 2002. In addition, selling, general and administrative expenses for the nine months ended September 30, 2005 include a one-time placement fee for the Chief Medical Officer position of \$54,000 which was filled in late June 2005. These expenses were offset in part by reductions in corporate overhead.

Interest income was \$90,000 for the nine months ended September 30, 2005 compared to \$38,000 for the same period in 2004. The increase is primarily the result of an increase in the cash and cash equivalents and an increase in the interest rate. Interest expense of \$132,000 was incurred during the nine months ended September 30, 2005 compared to \$102,000 for the same period in 2004. The increase is primarily due to the increase in the prime rate over the two periods from 4.00% in 2004 to 6.25% in 2005.

We recorded amortization of note discount of \$346,000 for each of the nine months ended September 30, 2005 and 2004. Of the \$346,000 expense, \$233,000 is due to the amortization of the \$1.5 million of discount resulting from the beneficial conversion feature of the convertible debt issued in March 2003 and \$113,000 is due to the amortization of the \$732,000 of discount associated with the below market stated interest rate.

### Liquidity and Capital Resources

As of September 30, 2005, we had cash and cash equivalents of \$4.3 million. The cash balance at September 30, 2005 includes the \$2.0 million payment received from Alticor in April 2005 as an advance payment for genetic tests to be processed under a distribution agreement. Net cash used in operating activities for the nine months ended September 30, 2005 was \$2.5 million compared to \$4.1 million for the same period in 2004. Cash was used primarily to fund operations.

Net cash used in investing activities was \$155,000 for the nine months ended September 30, 2005 compared to \$790,000 during the same period in 2004. Cash was used primarily for the purchase of equipment and capitalized patent costs.

Net cash provided by financing activities was \$2.4 million for the nine months ended September 30, 2005 compared to \$5.6 million for the nine months ended September 30, 2004. During 2005, we received \$2.2 million from our strategic alliance with Alticor and \$261,000 from the exercise of stock options and stock purchases through the employee stock purchase plan. These amounts were offset by \$11,000 of payments of our capital lease obligations. During 2004, we received \$5.0 million from our strategic alliance with Alticor and \$640,000 from the exercise of stock options and stock purchases through the employee stock purchase plan. These amounts were offset by \$19,000 of payments of our capital lease obligations.

We currently do not have any commitments for any material capital expenditures. Our obligations at September 30, 2005 for capital lease payments totaled \$6,000, all of which is classified as current. This capital lease obligation matures March 2006 at various interest rates.

A summary of our contractual obligations as of September 30, 2005 is included in the table below:

Contractual Obligations	Payments Due By Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Long-Term Debt Obligations (not including interest)	\$ 2,595,336	\$	\$ 2,595,336	\$	\$
Capital Lease Obligations	5,903	5,903			
Operating Lease Obligations	1,539,423	444,504	876,417	218,502	
<b>TOTAL</b>	<b>\$ 4,140,662</b>	<b>\$ 450,407</b>	<b>\$ 3,471,753</b>	<b>\$ 218,502</b>	<b>\$</b>

In March 2003, we entered into a broad strategic alliance with Alticor to develop and market personalized nutritional and skin care products. As part of the strategic alliance, we entered into a research

agreement (Research Agreement I) with Alticor, governing the terms of developing and validating nutrigenomic and dermagenomic tests and products. Alticor provided us with \$5.0 million during the twenty-four months ending March 31, 2005, to conduct certain research projects.

In June 2004, we entered into a research agreement (Research Agreement II) with Alticor, valued at \$2.2 million, to conduct research into the development of a test to identify individuals with specific genetic variations that affect how people gain and maintain weight. During the first phase of the agreement, we received \$1.4 million in research funding over a period of six months beginning on July 1, 2004. If Alticor determines, in its sole discretion, that it has a reasonable likelihood of commercializing weight management nutritional products, we will be eligible to receive, during the second phase of the agreement, an additional \$820,000 in funding over a six-month period.

In March 2005, we entered into an agreement with Alticor to expand the research being performed under Research Agreement I (Research Agreement III) to provide additional funding of \$2.7 million over the two years beginning April 1, 2005. Also in March 2005, we entered into an additional research agreement (Research Agreement IV) with Alticor for exploratory research valued at \$2.3 million over a two-year period commencing April 1, 2005. These research agreements are expected to provide us with a total of \$5.0 million during the two-year period ending March 2007.

In addition, in April 2005, Alticor paid us \$2.0 million as an advance payment for genetic risk assessment tests to be processed under the terms of a distribution agreement. Further, Alticor agreed to extend the loan period of the \$1.5 million working capital credit line through March 5, 2007.

We believe our current cash resources, together with anticipated funding from additional research agreements, anticipated revenue from product launches, and other arrangements are adequate to fund operations through mid-2006.

#### **Certain Factors That May Affect Future Results of Operations or the Market for Our Common Stock**

*We have a history of operating losses and expect these losses to continue in the future.*

We have experienced significant operating losses since our inception and expect these losses to continue for some time. We incurred losses from operations of \$5.1 million in 2002, \$5.9 million in 2003, \$6.7 million in 2004 and \$4.4 million for the nine months ended September 30, 2005. As of September 30, 2005, our accumulated deficit was \$59.4 million. Our losses result primarily from research and development and selling, general and administrative expenses. We have not generated significant revenue from product sales, and we do not know if we will ever generate sufficient revenue from product sales to cover our operating expenses. We will need to generate significant revenue to continue our research and development programs and achieve profitability. We cannot predict when, if ever, we will achieve profitability.

*The market for genetic risk assessment tests is unproven.*

The market for genetic risk assessment tests is at an early stage of development and may not continue to grow. The general scientific community, including us, has only a limited understanding of the role of genes in predicting disease. When we identify a gene or genetic marker that may predict disease, we conduct clinical trials to confirm the initial scientific discovery and to establish the scientific discovery's clinical utility in the marketplace. The results of these clinical trials could limit or delay our ability to bring the test to market, reduce the test's acceptance by our customers or cause us to cancel the program, any of which limit or delay sales and cause additional losses. The only genetic risk assessment test we currently market is PST®, and it has produced only minimal revenue to date. The marketplace may never accept our products, and we may never be able to sell our products at a profit. We may not complete development of or commercialize our other genetic risk assessment tests.

The success of our genetic risk assessment tests will depend upon their acceptance as medically useful and cost-effective by patients, physicians, dentists, other members of the medical and dental community and by third-party payers, such as insurance companies and the government. We can achieve broad market acceptance only with substantial education about the benefits and limitations of genetic risk assessment tests. Our tests may not gain market acceptance on a timely basis, if at all. If patients, dentists and physicians do not accept our tests, or take a longer time to accept them than we anticipate, then it will reduce our anticipated sales, resulting in additional losses.

*The market for personalized healthcare is unproven.*

The competition in the field of Personalized Health is not well defined due to a lack of an established market and customer base. The concept is new and requires consumers to do things differently, hence may be considered a disruptive technology. Adoption of such technology requires substantial market development and customer prospecting. There are a few companies offering predisposition tests or health risk assessments and product recommendations based upon these assessments. Activities in these areas remain small and the overall market is unproven. While both we and Alticor have done some initial market research regarding the marketability of these products there can be no assurance that these products will be successful upon launch or that they can be sold at sufficient margins to make them profitable to our partners or us. If customers do not accept our tests, or take a longer time to accept them than we anticipate, then it will reduce our anticipated sales, resulting in additional losses.

*We rely heavily on third parties to perform sales, marketing and distribution functions on our behalf, which could limit our efforts to successfully market products.*

We have limited experience and capabilities with respect to distributing, marketing and selling genetic risk assessment tests. We have relied and plan to continue to rely significantly on sales, marketing and distribution arrangements with third parties, over which we have limited influence. If these third parties do not successfully market our products, it will reduce our anticipated sales and increase our losses. If we are unable to negotiate acceptable marketing and distribution agreements with future third parties, or if in the future we elect to perform sales, marketing and distribution functions ourselves, we will incur significant costs and face a number of additional risks, including the need to recruit experienced marketing and sales personnel. In March 2003, we entered into a strategic alliance with Alticor. As part of this alliance, Alticor will conduct sales, marketing and distribution functions on our behalf. In February 2004, we received a purchase order from Alticor for a firm minimum order of genetic risk assessment tests to be delivered during the first year of product launch. While Alticor has far more experience and success in marketing, selling and distributing products than we do, we could become very dependent upon their success and their failure to successfully market our products could reduce our anticipated sales and increase our losses.

*If we fail to obtain additional capital, or obtain it on unfavorable terms, then we may have to end our research and development programs and other operations.*

We anticipate that our current and anticipated financial resources are adequate to maintain our current and planned operations through mid-2006. If we are not generating sufficient cash or cannot raise additional capital prior to that date, we will be unable to fund our business operations and will be required to seek other strategic alternatives.

Our future capital needs depend on many factors. We will need capital for the commercial launch of additional genetic tests, continued research and development efforts, obtaining and protecting patents and administrative expenses. Additional financing may not be available when needed, or, if available, it may not be available on favorable terms. If we cannot obtain additional funding on acceptable terms when needed, we may have to discontinue operations, or, at a minimum, curtail one or more of our research and development programs.

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*Because a single shareholder has a controlling percentage of our voting power, other stockholders' voting power is limited.*

As of September 30, 2005, a single stockholder owned, or had rights to own approximately 57.6% of our outstanding common stock. Accordingly, this stockholder will be able to determine the outcome of stockholder votes, including votes concerning the election of directors, the adoption or amendment of provisions in our Certificate of Incorporation or By-Laws and the approval of certain mergers and other significant corporate transactions, including a sale of substantially all of our assets. This stockholder may make decisions that are adverse to other stockholders' or warrant holders' interests. This ownership concentration may also adversely affect the market price of our common stock. Three of our four directors are individuals chosen by this single stockholder. These directors might pursue policies in the interest of this single stockholder to the detriment of our other stockholders.

*The Series A Preferred Stock has certain rights which are senior to common shareholder rights and this may reduce the value of the common stock.*

The Series A Preferred Stock, which was issued to Alticor in March 2003, accrues dividends at the rate of 8% of the original purchase price per year, payable only when, as and if declared by the Board of Directors and are non-cumulative. If we declare a distribution, with certain exceptions, payable in securities of other persons, evidences of indebtedness issued by us or other persons, assets (excluding cash dividends) or options or rights to purchase any such securities or evidences of indebtedness, then, in each such case the holders of the Series A Preferred Stock shall be entitled to a proportionate share of any such distribution as though the holders of the Series A Preferred Stock were the holders of the number of shares of our common stock into which their respective shares of Series A Preferred Stock are convertible as of the record date fixed for the determination of the holders of our common stock entitled to receive such distribution.

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of the Series A Preferred Stock shall be entitled to receive, prior and in preference to any distribution of any of our assets or surplus funds to the holders of our common stock by reason of their ownership thereof, the amount of two times the then-effective purchase price per share, as adjusted for any stock dividends, combinations or splits with respect to such shares, plus all declared but unpaid dividends on such share for each share of Series A Preferred Stock then held by them. After receiving this amount, the holders of the Series A Preferred Stock shall participate on an as-converted basis with the holders of common stock in any of our remaining assets.

The preferential right of the Series A Preferred Stock might reduce the value of the common stock.

*If we are unsuccessful in establishing additional strategic alliances, our ability to develop and market products and services will be damaged.*

Entering into strategic alliances for the development and commercialization of products and services based on our discoveries is an important element of our business strategy. We anticipate entering into additional collaborative arrangements with Alticor and other parties in the future. We face significant competition in seeking appropriate collaborators. In addition, these alliance arrangements are complex to negotiate and time-consuming to document. If we fail to maintain existing alliances or establish additional strategic alliances or other alternative arrangements, then our ability to develop and market products and services will be damaged. In addition, the terms of any future strategic alliances may be unfavorable to us or these strategic alliances may be unsuccessful.

*If we fail to obtain an adequate level of reimbursement for our products or services by third-party payers, then our products and services will not be commercially viable.*

The availability and levels of reimbursement by governmental and other third-party payers affect the market for any healthcare service. These third-party payers continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for medical products and services. To the extent that our products are sold through the medical channel, our ability to successfully commercialize our existing genetic risk assessment test and others that we may develop depends on obtaining adequate reimbursement from third-party payers. The extent of third-party payer reimbursement will likely heavily influence physicians' and dentists' decisions to recommend genetic risk assessment tests, as well as patients' elections to pursue testing. If reimbursement is unavailable or limited in scope or amount, then we cannot sell our products and services profitably. In particular, third-party payers tend to deny reimbursement for services which they determine to be investigational in nature or which are not considered reasonable and necessary for diagnosis or treatment. To date, few third-party payers have agreed to reimburse patients for genetic risk assessment tests, and we do not know if third-party payers will, in the future, provide full reimbursement coverage for these genetic tests. If third-party payers do not provide adequate reimbursement coverage, then individuals may choose to directly pay for the test. If both third-party payers and individuals are unwilling to pay for the tests, then the number of tests we can sell will be significantly decreased, resulting in reduced revenue and additional losses.

*If we fail to obtain patent protection for our products and preserve our trade secrets, then competitors may develop competing products and services, which will decrease our sales and market share.*

Our success will partly depend on our ability to obtain patent protection, in the United States and in other countries, for our products and services. In addition, our success will also depend upon our ability to preserve our trade secrets and to operate without infringing upon the proprietary rights of third parties.

We own exclusive rights in seventeen issued U.S. patents and have a number of additional U.S. patent applications pending. We have also been granted a number of corresponding foreign patents and have a number of foreign counterparts of our U.S. patents and patent applications pending. Our patent positions, and those of other pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific and factual questions. Our ability to develop and commercialize products and services depends on our ability to:

- Obtain patents;
- Obtain licenses to the proprietary rights of others;
- Prevent others from infringing on our proprietary rights; and
- Protect trade secrets.

Our pending patent applications may not result in issued patents and any issued patents may never afford meaningful protection for our technology or products. Further, others may develop competing products, which avoid legally infringing upon, or conflicting with, our patents. In addition, competitors may challenge any patents issued to us, and these patents may subsequently be narrowed, invalidated or circumvented.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, by confidentiality agreements. The third parties we contract with may breach these agreements, and we might not have adequate remedies for any breach. Additionally, our competitors may discover or independently develop our trade secrets.

*Third parties may own or control patents or patent applications and require us to seek licenses, which could increase our costs or prevent us from developing or marketing our products or services.*

We may not have rights under patents or patent applications that are related to our current or proposed products. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, to develop or sell any proposed products or services, with patent rights controlled by third parties, our collaborators or we may seek, or may be required to seek, licenses under third-party patents and patent applications. If this occurs, we will pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, our collaborators or we may be prohibited from developing or selling our products or services.

If third parties believe our products or services infringe upon their patents, they could bring legal proceedings against us seeking damages or seeking to enjoin us from testing, manufacturing or marketing our products or services. Any litigation could result in substantial expenses to us and significant diversion of attention by our technical and management personnel. Even if we prevail, the time, cost and diversion of resources of patent litigation would likely damage our business. If the other parties in any patent litigation brought against us are successful, in addition to any liability for damages, we may have to cease the infringing activity or obtain a license.

*Technological changes may cause our products and services to become obsolete.*

Our competitors may develop risk assessment tests that are more effective than our technologies or that make our technologies obsolete. Innovations in the treatment of the diseases in which we have products or product candidates could make our products obsolete. These innovations could prevent us from selling, and significantly reduce or eliminate the markets for, our products.

*We may be prohibited from fully using our net operating loss carryforwards, which could affect our financial performance.*

As a result of the losses incurred since inception, we have not recorded a federal income tax provision and have recorded a valuation allowance against all future tax benefits. As of December 31, 2004, we had net operating loss carryforwards of approximately \$39.5 million for federal and state income tax purposes, expiring in varying amounts through the year 2024. We also had a research tax credit of approximately \$761,000 at December 31, 2004 that expires in varying amounts through the year 2024. Our ability to use these net operating loss and credit carryforwards is subject to restrictions contained in the Internal Revenue Code which provide for limitations on our utilization of our net operating loss and credit carryforwards following a greater than 50% ownership change during the prescribed testing period. We have experienced two such ownership changes. One change arose in March 2003 and the other was in June 1999. As a result, all of our net operating loss carryforwards will be limited in utilization. The annual limitation may result in the expiration of the carryforwards prior to utilization. In addition, in order to realize the future tax benefits of our net operating loss and tax credit carryforwards, we must generate taxable income, of which there is no assurance.

*We are subject to intense competition from other companies, which may damage our business.*

Our industry is highly competitive. Our competitors in the United States and abroad are numerous and include major pharmaceutical and diagnostic companies, specialized biotechnology firms, universities and other research institutions, including those receiving funding from the Human Genome Project. Many of our competitors have considerably greater financial resources, research and development staffs, facilities, technical personnel, marketing and other resources than we do. Furthermore, many of these competitors are more experienced than we are in discovering, commercializing and marketing products. These greater resources may allow our competitors to discover important genes or genetic markers before

we do. If we do not discover disease predisposing genes and commercialize these discoveries before our competitors, then our ability to generate sales and revenue will be reduced or eliminated, and could make our products obsolete. We expect competition to intensify in our industry as technical advances are made and become more widely known.

*We are subject to government regulation which may significantly increase our costs and delay introduction of future products.*

The sale, performance and analyses of our genetic tests do not currently require FDA or other federal regulatory approval. Changes in existing federal law or regulations could require pre-market approval of genetic risk assessment tests, possibly resulting in a curtailment or even prohibition of our activities. If our genetic tests become subject to new levels of regulatory approval, on either a state or federal level, then the costs of developing and marketing them will increase and the time to market could increase. We anticipate that the tests will be performed primarily in our own laboratory which is certified under the auspices of the Clinical Laboratory Improvement Act of 1988 ( CLIA ), administered by the Health Care Financing Administration. We will need to register our testing laboratory in a number of states. We anticipate there will also be additional state and local regulations governing the operation of this laboratory with which we will have to comply. In particular, we will be subject to the laws and regulations of Massachusetts, the state in which the laboratory operates. A delay in receiving CLIA certification or any applicable state or local certification would reduce our revenue and increase our net losses. The operation of our testing laboratory carries with it the risk of incurring one or more lawsuits for negligence.

*We may be subject to product liability claims that are costly to defend and that could limit our ability to use some technologies in the future.*

The design, development, manufacture and use of our genetic risk assessment tests involve an inherent risk of product liability claims and associated adverse publicity. Producers of medical products face substantial liability for damages in the event of product failure or allegations that the product caused harm. We currently maintain product liability insurance, but it is expensive and difficult to obtain, may not be available in the future on economically acceptable terms and may not be adequate to fully protect us against all claims. We may become subject to product liability claims that, even if they are without merit, could result in significant legal defense costs. We could be held liable for damages in excess of the limits of our insurance coverage, and any claim or resulting product recall could create significant adverse publicity.

*Ethical, legal and social issues related to genetic testing may reduce demand for our products.*

Genetic testing has raised issues regarding the appropriate utilization and the confidentiality of information provided by genetic testing. Genetic tests for assessing a person's likelihood of developing a chronic disease have focused public attention on the need to protect the privacy of genetic assessment medical information. For example, concerns have been expressed that insurance carriers and employers may use these tests to discriminate on the basis of genetic information, resulting in barriers to the acceptance of genetic tests by consumers. This could lead to governmental authorities prohibiting genetic testing or calling for limits on or regulating the use of genetic testing, particularly for diseases for which there is no known cure. Any of these scenarios would decrease demand for our products and result in substantial losses.

*Our failure to timely assess and report on the effectiveness of our internal control over financial reporting in accordance with U.S. federal securities laws and the resulting disclaimer from our independent registered public accounting firm may expose us to regulatory sanctions and cause a loss of investor confidence in our internal controls, and adversely affect the trading price of our shares.*

Because our public common float exceeded \$75 million on June 30, 2004, we became obligated to comply with Section 404 of Sarbanes-Oxley Act of 2002 for the fiscal year ended December 31, 2004. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting as of the fiscal year end and a report by our independent registered public accounting firm of their opinion on our assessment. Management did not complete its work related to the year ended December 31, 2004 prior to the initial filing of our Annual Report on Form 10-K and, because of this, at that time Grant Thornton LLP was unable to, and did not, express an opinion on management's assessment of its internal control over financial reporting for our fiscal year ended December 31, 2004. In June 2005, management completed its assessment and Grant Thornton LLP expressed its opinion with respect to that assessment, and we amended our Annual Report on Form 10-K for the year ended December 31, 2004 accordingly. However, our failure to timely complete our assessment of our internal control over financial reporting, identify and remediate any material weakness that may exist, and our auditors' opinion on management's assessment could expose us to regulatory sanctions or cause a loss of investor confidence in our internal controls, and in turn might adversely affect the market price of our common stock.

*Our dependence on key executives and scientists could adversely impact the development and management of our business.*

Our success substantially depends on the ability, experience and performance of our senior management and other key personnel. If we lose one or more of the members of our senior management or other key employees, it could damage our development programs and our business. In addition, our success depends on our ability to continue to hire, train, retain and motivate skilled managerial and scientific personnel. The pool of personnel with the skill that we require is limited. Competition to hire from this limited pool is intense. We compete with numerous pharmaceutical and healthcare companies, as well as universities and nonprofit research organizations in the highly competitive Boston, Massachusetts business area. Loss of the services of Dr. Philip R. Reilly, our Chief Executive Officer, or Dr. Kenneth Kornman, our President and Chief Scientific Officer, or Dr. Ramon Mohanlal, our Chief Medical Officer, could delay our research and development programs or otherwise damage our business. In March 2003, we entered into employment agreements with three-year terms with Dr. Reilly and Dr. Kornman. Each of these employees can terminate his employment upon 30 days notice. We do not maintain key man life insurance on any of our personnel.

*In a circumstance in which Alticor enters a business in competition with our own, our Directors might have a conflict of interest.*

In conjunction with our strategic alliance with Alticor, we have agreed to certain terms for allocating opportunities as permitted under Section 122(17) of the Delaware General Corporation Law. This agreement regulates and defines the conduct of certain of our affairs as they may involve Alticor as our majority stockholder and its affiliates, and the powers, rights, duties and liabilities of us and our officers and directors in connection with corporate opportunities.

Except under certain circumstances, Alticor and its affiliates have the right to engage in the same or similar activities or lines of business or have an interest in the same classes or categories of corporate opportunities as we do. If Alticor or one of our directors appointed by Alticor, and its affiliates acquire knowledge of a potential transaction or matter that may be a corporate opportunity for both Alticor and its affiliates and us, to the fullest extent permitted by law, Alticor and its affiliates will not have a duty to



inform us about the corporate opportunity or be liable to us or to you for breach of any fiduciary duty as a stockholder of ours for not informing us of the corporate opportunity, keeping it for its own account, or referring it to another person.

Additionally, except under limited circumstances, if an officer or employee of Alticor who is also one of our directors is offered a corporate opportunity, such opportunity shall not belong to us. In addition, we agreed that such director will have satisfied his duties to us and not be liable to us or to you in connection with such opportunity.

The terms of this agreement will terminate on the date that no person who is a director, officer or employee of ours is also a director, officer, or employee of Alticor or an affiliate.

*We do not expect to pay dividends for the foreseeable future and you should not expect to receive any funds without selling your shares of common stock, which you may only be able to do at a loss.*

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Therefore, you should not expect to receive any funds without selling your shares, which you may only be able to do at a loss.

### **Effects of Inflation**

We believe that inflation and changing prices over the past three years have not had a significant impact on our net revenue or on our income from continuing operations.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risk related to changes in interest rates and foreign currency exchange rates. We do not use derivative financial instruments for speculative or trading purposes.

#### *Interest Rate Risk*

We are exposed to market risk from changes in interest rates primarily through our financing activities. Interest on our notes payable accrues at a rate equal to the prime rate of interest plus 1% per annum. Our ability to carry out our business plan or our ability to finance future working capital requirements may be impacted if the cost of carrying debt fluctuates to the point where it becomes a burden on our resources.

#### *Foreign Currency Risk*

Some of our sales occur outside the United States and are transacted in foreign currencies. Accordingly, we are subject to exposure from adverse movements in foreign currency exchange rates. At this time we do not believe this risk is material and we do not currently use derivative financial instruments to manage foreign currency fluctuation risk. However, if foreign sales increase and the risk of foreign currency exchange rate fluctuation increases, we may in the future consider utilizing derivative instruments to mitigate these risks.

### **Item 4. Controls and Procedures**

(a) *Evaluation of Disclosure Controls and Procedures.* Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Quarterly Report on Form 10-Q, have concluded that, based on such evaluation, our disclosure controls and procedures were adequate and effective to ensure that material information relating to us, including our consolidated

subsidiaries, was made known to them by others within those entities, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared.

In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(b) *Changes in Internal Control Over Financial Reporting.* Management and our independent accountants have identified several material weakness in our internal control over financial reporting that are described in our Annual Report on Form 10-K for the year ended December 31, 2004, as amended. Because of these material weaknesses, management believes and our independent accountants agree that, as of December 31, 2004, the Company's internal control over financial reporting was not effective. To date, management has continued to take corrective actions to address the material weaknesses identified. These actions include:

- *Assessment of the Effectiveness of Internal Controls* Management has engaged a consultant to assist in the evaluation of internal controls in 2005 and the documentation of the tests performed to provide reasonable assurance that the controls are operating effectively.
- *Evidence of Management Review and Monitoring Controls.* Management has implemented new procedures that require documentation of evidence, such as signatures of reviews performed.
- *Application of U.S. GAAP* Management has implemented new procedures requiring the documentation of the application of U.S. GAAP for any significant transactions and the review of such documentation by persons with the adequate knowledge and expertise with respect to the requirements and application of U.S. GAAP.
- *Segregation of Duties* Management has and will continue to evaluate the segregation of duties issue by examining the employees involved and the control procedures in place to determine whether the potential benefits of adding new employees to clearly segregate duties justifies the expense associated with such increases. In addition, the Company has implemented compensating controls such as management oversight where resource constraints compromise the ability to segregate duties.

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings.**

We are not aware of any current or pending litigation to which we are or may be a party to that we believe could materially adversely affect our results of operations or financial condition or net cash flows.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

Not applicable.

**Item 3. Defaults Upon Senior Securities.**

Not applicable.

**Item 4. Submission of Matters to a Vote of Security Holders.**

Not applicable.

**Item 5. Other Information.**

Not applicable.

**Item 6. Exhibits.**

The exhibits listed in the Exhibit Index immediately preceding the exhibits are filed as part of this Quarterly Report on Form 10-Q.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 4, 2005	INTERLEUKIN GENETICS, INC. By:	/s/ PHILIP R. REILLY Philip R. Reilly Chairman of the Board and Chief Executive Officer (Principal Executive Officer)
Date: November 4, 2005	By:	/s/ JOHN J. MCCABE John J. McCabe Controller and Chief Accounting Officer (Principal Financial Officer)

**EXHIBIT INDEX**

**Exhibit**

**Number**

**Exhibit**

31.1*	Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification by Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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\* Filed herewith.

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